



Nitrosamine Testing - UKAS

N-Nitrosamines are formed from secondary amines which are generated by the decomposition of certain rubber accelerators and which react with nitrous oxides during mixing and curing. They are known animal carcinogens and there are a number of regulations in existence on the following products or areas:

Nitrosamine testing Bottle teats:

FDA nitrosamines testing – solvent extraction.

The FDA allows a total of 60ppb but will take action when any individual nitrosamine is present at a level of 10ppb or more. No further regulations regarding bottle teats or any other product are known to exist in the USA or Canada.

CEN nitrosamine testing to BSEN 12868 – artificial saliva extraction.

The European Directive 93/11/EEC states that migration into the test medium must not exceed 10µg/kg for nitrosamines and 100 µg/kg for nitrosatable amines.

Nitrosamine testing Balloons:

BgVV/BfR

Bundesgesundhbl 3/97 has an advisory 10 µg/kg limit for nitrosamines in balloons and stipulates 5 µg/dm² for nitrosatable amines after 1 hour extraction.

Nitrosamine testing Condoms:

BgVV/BfR

Bundesgesundheitsamt 24.04.1992 offers an "explanation and supplement" to a publication of 24.11.89. This (1992) document states that condoms must meet the 15.12.81 limits set for teats/soothers.

Nitrosamine testing Food contact:

BgVV/BfR

Bundesgesundhbl 10/94 is a complex announcement on rubber in contact with food. A similar regulation is currently being discussed in Europe

Airborne Nitrosamine testing: TRGS 552

These limits for working atmospheres are in place in Germany only, but are sometimes used as guidelines by other countries wishing to address the issue in production and storage areas. The TRGS 552 guidelines state a maximum of 1µg/m³ since 1991, but it seems the earlier 1989 limit of 2.5 µg/m³ is still permitted near presses or in the mixing area provided increased personal protection is given.

Rubber Consultants offers a testing service for all the categories above using UKAS accredited nitrosamines testing methods to ISO 17025.

To use these services or for more information please contact sstephens@tarrc.co.uk